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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/693,383	10/24/2003	Shalaby W. Shalaby	PC25203A	1654

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PFIZER INC
150 EAST 42ND STREET
5TH FLOOR - STOP 49
NEW YORK, NY 10017-5612

EXAMINER

SILVERMAN, ERIC E

ART UNIT PAPER NUMBER

1615

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/693,383

Applicant(s)

SHALABY ET AL.

Examiner

Eric E. Silverman, PhD

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1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>5-25-07</u> . | 6) <input type="checkbox"/> Other: ____. |

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DETAILED ACTION

Applicants' response, filed 5/25/2007, has been received. Claims 1 – 15 are pending in this action.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1 – 15 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 – 13 of copending Application No. 10/693,307. Although the conflicting claims are not identical, they are not patentably distinct from each other because instant claims specify a solid conjugate, whereas the conjugates of copending application are "liquid". However, it is clear that the term liquid conjugate, as used in copending claims, includes solid conjugates that are dissolved in water. Thus, the claims substantially overlap and copending claims render instant claims obvious.

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This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

Claims 1 – 4, 6 – 8, and 11 – 15 **remain** rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement for reasons of record and those discussed below.

Response to Arguments

Applicants' arguments have been fully considered, but they are not persuasive. Applicants' argue that the artisan would know what is meant by "pharmaceutical compound", and further, that the artisan would know which pharmaceutical compounds could form ionic conjugates according to the present invention. In response, while it is true that the meaning of the term "pharmaceutical compound" is known in the art, it is the position of the office that the artisan is afforded sufficient description of the invention to recognize which pharmaceutical compounds are actually useful in the instant invention, and thus, what applicants' actually had possession of. The specification provides no guidance as to which pharmaceutical compounds could be used in the invention, it merely points out certain functional groups which are believed to be capable of ionic conjugation with the generic "functional polymer" of the claims. However, this general teaching is not a showing of what materials actually work in the invention; rather it is a hunting license giving the artisan little more than an invitation to experiment and try on their own to determine which pharmaceutical compounds are actually useful. Such an invitation to experiment is not sufficient to satisfy the provisions of this section.

The same principle applies with respect to the "functional polymer". The specification only points out some functional groups which, if present on polymers, may or may not be useful in making the claimed invention. Again, this is little more than an invitation to experiment, and does not constitute a full written description of the invention.

Claim Rejections - 35 USC § 102

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, 4 – 7 **remain** rejected under 35 U.S.C. 102(a) or 102(e) as being anticipated by US 6,232,304 to Kim et al.

Response to Arguments

Applicants' arguments have been fully considered, but they are not persuasive. Applicants' first argue that the cyclodextrins of are not polymeric. Applicants' point out that cyclodextrins typically have seven repeating units and are cyclical. Applicants' believe that cyclodextrins may be oligomers, but are not polymers. In response, cyclodextrins are cyclopolymers with a degree of polymerization of (typically) seven. A material with a degree of polymerization of seven is a polymer, using the broadest reasonable interpretation of that term. Applicants' also aver that cyclodextrins are not necessarily ionic, and that Kim's conjugates are not believed to be ionic. It is noted however that upon interaction with water and the various functional groups in ziprasidone, the basic amines of cyclodextrins will indeed form ionic conjugates.

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Neither compound need be ionic itself for the conjugate to be ionic. For example, interaction of the amine base (on the cyclodextrin) with the hydrate of ziprasidone's ketone is one ionic mode of interaction. Another is protonation of the cyclodextrin amine by water and interaction of the ammonium group with the amine base or the ketone oxygen of ziprasidone in a Lewis acid-Lewis base type interaction. Once the office has shown by technical reasoning why a feature of the art is inherent (in this case, that the conjugates will be ionic), Applicants' must show evidence to prove that this showing is incorrect. The evidence provided by Applicants (in the form of the Kibbe reference) only speaks to the cyclodextrins themselves, not the conjugates formed with ziprasidone.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 3, 8, and 11 – 14 **remain** rejected under 35 U.S.C. 103(a) as being unpatentable over Kim in view US 5,916,883 to Shalaby et al.

Response to Arguments

Applicants' arguments have been fully considered, but they are not persuasive. Applicants' argue that the conjugates of Shalaby are actually less soluble than the original materials, and that there is no motivation to combine Kim and Shalaby for this reason. Applicants' point to example 3 in Shalaby, where the drug is first dissolved in

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acetone, and the conjugate is precipitated in *ice water*. In response, this example is not a reasonable comparison of the aqueous solubility of the drug before and after conjugation. Solubility in acetone is not a reflection of solubility in water, in fact, it is reasonable to conclude that if the (unconjugated) drugs were soluble in water, then acetone would not have been used as a solvent. Further, precipitation in *ice water* does not reasonably show that a conjugate is insoluble in water at room temperatures. Indeed, if the conjugate were insoluble in water at room temperature, an ice-water bath would not be needed for precipitation, and room temperature water would be used. Since Shalaby actually provides no real teaching concerning the solubility, the artisan would expect that, according to Kim, an increase in solubility would be the result of using the materials of Shalaby.

Conclusion

Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on 5/25/07 prompted the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 609.04(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Eric E. Silverman, PhD
Art Unit 1615


MICHAEL P. WOODWARD
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600